

### REMARKS

The May 4, 2006 Official Action has been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset it is noted that a shortened statutory response period of three (3) months was set forth in the May 4, 2006 Official Action. Therefore, the initial due date for response is August 6, 2006.

The Examiner has indicated that claims 6-9 are free of the prior art. However, claims 6-9 have been objected to as being dependent on a rejected base claim.

Claim 5 has been rejected for allegedly failing to satisfy the written description and enablement requirements of 35 U.S.C. §112, first paragraph. It is the Examiner's position that the specification fails to provide all of the necessary and sufficient structural elements of the NEP and PEP promoters. The Examiner also contends that the specification fails to provide guidance for NEP promoters from genes other than *clpP*, *rpoB*, and *atpB* and for PEP promoters from genes other than *clpP*.

Lastly, the Examiner has rejected claim 5 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 5,877,402 as evidenced by Legen et al. (Plant J. (2002) 31:171-188). The '402 patent discloses a construct comprising the *rps16* promoter operably linked to the *uidA* coding region and Legen et al. allegedly teach that the *rps16* promoter comprises both a PEP and NEP promoter.

The foregoing objection and rejections constitute all of the grounds set forth in the May 4, 2006 Official Action for refusing the present application.

In accordance with the instant amendment, claims 10-11 have been added. Support for claim 10 can be found throughout the specification including, for example, in Example I and Figure 5. Example IV provides support for claim

11.

No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the present amendment and the reasons set forth in this response, Applicants respectfully submit that the objection to claims 6-9; the 35 U.S.C. §112, first paragraph rejections of claim 5; and the 35 U.S.C. §102(e) rejection of claim 5, as set forth in the May 4, 2006 Official Action, cannot be maintained. These grounds of objection and rejection are, therefore, respectfully traversed.

**CLAIM 5 MEETS THE REQUIREMENTS OF  
35 U.S.C. §112, FIRST PARAGRAPH**

The Examiner has rejected claim 5 for allegedly failing to satisfy the written description and enablement requirements of 35 U.S.C. §112, first paragraph. It is the Examiner's position that the specification fails to provide all of the necessary and sufficient structural elements of the NEP and PEP promoters. The Examiner also contends that the specification fails to provide guidance for NEP promoters from genes other than *clpP*, *rpoB*, and *atpB* and for PEP promoters from genes other than *clpP*.

Applicants respectfully disagree with the Examiner's position for all of the reasons already set forth in the February 3, 2006 Official Action response and those set forth below.

The Examiner contends the specification lacks written description of the structural and functional characteristics of the claimed compositions. Applicants respectfully disagree. The instant specification teaches that NEP promoters are those which are transcribed by a plastid-localized, nuclear-encoded polymerase and that PEP promoters are transcribed by a plastid encoded polymerase. Accordingly,

the instant specification clearly provides the function of the NEP and PEP promoters. Furthermore, the instant specification provides several examples of NEP and PEP promoters as indicated in the previous Official Action response.

Notably, a single species can satisfy the written description requirement of a genus is explicitly recognized in the "SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES" (<http://www.uspto.gov/web/menu/written.pdf>). For example, Example 9 indicates that the written description requirement is satisfied by the disclosure of a single species, in particular a single nucleotide sequence, for a claim drawn to sequences closely structurally related to the single sequence. Further, the guidelines teach that a "single disclosed species is representative of the genus because reduction to practice of this species, considered along with the defined hybridization conditions and the level of skill and knowledge in the art, are sufficient to allow the skilled artisan to recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus" (see Example 10).

Therefore, considering 1) the disclosure of multiple species of NEP promoters and PEP promoters, 2) the disclosure of the functions of the NEP and PEP promoters, and 3) the ability to identify other NEP and PEP promoters (see Examples I-IV), it is respectfully submitted that one of skill in the art would recognize that the NEP and PEP promoters falling within the claims are indeed disclosed by the entire teaching of the specification. Nothing more is required under 35 U.S.C. §112, first paragraph.

With regard to the enablement rejection, the Examiner contends that "undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims, to identify those that are NEP and PEP promoters." Applicants respectfully disagree. The MPEP at §2164.01 states that "the fact that

experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." Applicants submit that Examples I-IV of the instant specification provides methods for the identification of NEP and PEP promoters and that the experimentation needed to do so are typically performed by those skilled in the art. Accordingly, Applicants respectfully submit that no undue experimentation would be needed to practice the full breadth of the instantly claimed invention.

In light of all of the foregoing, Applicants respectfully submit that the rejections of claim 5 under 35 U.S.C. §112, first paragraph are untenable and respectfully request their withdrawal.

#### **CLAIM 5 IS NOT ANTICIPATED BY THE '402 PATENT**

The Examiner has rejected claim 5 under 35 U.S.C. §102(e) as allegedly anticipated by the '402 patent as evidenced by Legen et al. Specifically, is the Examiner's position that the '402 patent discloses a construct comprising the rps16 promoter operably linked to the uidA coding region and that Legen et al. teach that the rps16 promoter comprises both a PEP and NEP promoter.

Applicants continue to disagree with the Examiner for the reasons set forth in the February 3, 2006 Official Action response. Legen et al. state that various genes, including rps16, "display higher relative transcription rates" in wild-type leaf tissue than in mutant leaf tissue which are deficient in PEP. The Examiner argues that the "lower expression in the PEP-lacking mutant indicates that rps16 has a PEP promoter, as well as an NEP promoter." Applicants respectfully disagree. Legen et al. is wholly silent as to the presence of a NEP promoter in the rps16 promoter. Further, the higher transcription rates seen in wild-type leaf tissue than in mutant leaf tissue which are deficient in PEP could also be accounted for by a promoter containing only a

PEP promoter. Indeed, a promoter containing a PEP promoter and not an NEP promoter would exhibit "higher relative transcription rates" in wild-type leaf tissue than in mutant leaf tissue which are deficient in PEP. As stated in the February 3, 2006 Official Action response, the MPEP at §2131.01(III) states that "to serve as an anticipation when the reference is silent about the asserted inherent characteristic, ... [the provided] evidence **must** make clear that the missing descriptive matter is **necessarily** present in the thing described in the reference" (emphasis added). Inasmuch as Legen et al. fail to show that the NEP promoter is **necessarily** present in the rps16 promoter, Applicants submit that the Examiner has failed to establish a proper rejection under 35 U.S.C. §102(e).

In view of the foregoing, Applicants respectfully submit that the instant rejection of claim 5 is untenable and should be withdrawn.

#### CONCLUSION

It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

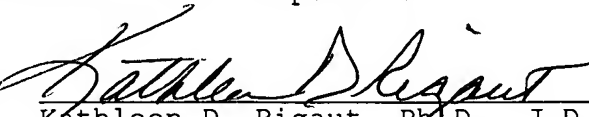
In view of the amendments presented herewith, and the foregoing remarks, it is respectfully urged that the objection and rejections set forth in the May 4, 2006 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding

issues may be resolved through a telephone interview, the Examiner is requested to call the undersigned at the phone number given below.

Respectfully submitted,  
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